MAY 12 2000

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SECTION 10
510(K) SUMMARY

FOI RELEASABLE

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation chooses to submit a summary of information respecting safety and effectiveness.

- DATE: January 28, 2000
- COMMON/USUAL NAMES: Enteral Prosthesis
- TRADE/PROPRIETARY NAME: Wallstent® Enteral Prostheseis
- CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class III

Name	Number	21 CFR Ref.
Esophageal Prosthesis	78 MQR	878.3610

- DEVICE PANEL/BRANCH: Gastroenterology-Urology (GU)
  Gastro-Renal (GRDB)
- OWNER/OPERATOR: Boston Scientific Corporation
  One Boston Scientific Place
  Natick, MA 01760
- CONTACT PERSON: Lisa M. Quaglia, Regulatory Affairs Manager

DESCRIPTION OF DEVICE

The Wallstent® Enteral Endoprosthesis is comprised of two components: the implantable metallic stent and the Unistep™ Plus Delivery system (reference Figure A). The stent is composed of biomedical super alloy monofilament wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during deployment. Radiopaque marker bands situated adjacent to the leading and trailing ends of the stent facilitate imaging during deployment. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035 in. / 0,89 mm guide wire. The device may be inserted through the working channel of an endoscope (minimum channel diameter 3.7 mm).

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INDICATIONS FOR USE

The Wallstent® Enteral Endoprosthesis with Unistep™ Plus Delivery system is for palliative treatment of colonic or duodenal strictures or gastric outlet obstruction caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in malignant strictures. list indications

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the Modified Enteral Wallstent® is substantially equivalent to the currently-marketed Enteral Wallstent®. The major components of the Modified Enteral Wallstent® are the stent and the delivery system. A thorough comparison of the descriptive characteristics between the Modified Enteral Wallstent® and the predicate device show equivalence.

PERFORMANCE CHARACTERISTICS

Laboratory testing regarding characteristics was performed on Modified Enteral Wallstent® to verify its safety and performance. A biocompatibility assessment was performed on the patient- and fluid-contact materials of the Modified Enteral Wallstent® with satisfactory results.

CONCLUSION

Boston Scientific Corporation believes that Modified Enteral Wallstent® is substantially equivalent to the currently-marketed Enteral Wallstent®. A comparison of the descriptive characteristics of these products demonstrate the Modified Enteral Wallstent® is equivalent in its indications for use, while being very similar in design and materials. In addition, Boston Scientific Corporation has presented laboratory testing and biocompatibility information. The information presented provides assurance that the Modified Enteral Wallstent® will meet the minimum requirements that are considered acceptable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2000

Ms. Lisa M. Quaglia
Regulatory Affairs Manager
Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

Re: K000281
Modified Enteral Wallstent®
Dated: March 23, 2000
Received: March 24, 2000
Regulatory Class: II
21 CFR §878.3610/Procode: 78 MQR
21 CFR §878.3610/Procode: 78 MUM

Dear Ms. Quaglia:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

SECTION 1
INDICATIONS FOR USE

510(k) Number: ~~To Be Determined~~ K000281/S001

Device Name: Modified Enteral Wallstent®

Indication for Use:

The Wallstent® Enteral Endoprosthesis with Unistep™ Plus Delivery system is indicated for palliative treatment of colonic or duodenal strictures or gastric outlet obstruction caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000281

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.1091)

(Optional Format 1-2-96)